

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

A comparison between the effectiveness and safety of the combination of Licodain spray and vapocolant spray, and Licodain spray alone in local anesthesia during iv catheterization

Protocol summary

Study aim

Determining and comparing the local anesthetic effect of lidocaine spray along with Power Ice Deltazax cooling spray with lidocaine spray during venous catheterization

Design

A controlled, parallel-group, single-blind clinical trial. Randomized phase 2 on 116 patients Dice is used for randomization.

Settings and conduct

Boali hospital emergency room, The samples were divided into 2 groups: 1- intervention with lidocaine spray along with Deltazax PowerIce cooling spray and 2- intervention group with lidocaine spray alone. Blinding is one-way blinding and the patient does not know the group he is in and the medicine used

Participants/Inclusion and exclusion criteria

- Criteria for entering the study: Patients requiring intravenous injections Age above 18 years Alert and able to communicate No history of psychiatric disorders Do not use any topical medication Do not take painkillers for 12 hours before venipuncture Willingness and informed consent to participate in the study - Exclusion criteria: Lack of consent to enter the study Addiction to opioids Addiction to strong painkillers History of allergy to any of the drugs used Sensitivity to cold A history of panic attacks Patients with peripheral vascular diseases Patients with sensory disorders such as peripheral neuropathy Unwillingness to continue participating in the study

Intervention groups

1- the intervention with lidocaine spray along with PowerIce Deltazax cooling spray 2- the intervention group with lidocaine spray alone will be divided.

Main outcome variables

intensity of pain, Increased heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200707048047N3**

Registration date: **2023-03-01, 1401/12/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-01, 1401/12/10**

Update count: **0**

Registration date

2023-03-01, 1401/12/10

Registrant information

Name

Masoumeh Moallem

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2611 6628

Email address

masoumehmoallem@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-05, 1401/11/16

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between the effectiveness and safety of the combination of Licodain spray and vapocolant spray, and Licodain spray alone in local anesthesia during iv catheterization

Public title

The effect of lidocaine spray and vapocolant spray in reducing the pain of venous catheterization

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness and informed consent to participate in the study
Age above 18 years
Alert and able to communicate
No history of psychiatric disorders
Do not use any topical medication
Do not take painkillers for 12 hours before venipuncture
Willingness and informed consent to participate in the study

Exclusion criteria:

Lack of consent to enter the study
Addiction to opioids
Addiction to strong painkillers
History of allergy to any of the drugs used
Sensitivity to cold
A history of panic attacks
Patients with peripheral vascular diseases
Patients with sensory disorders such as peripheral neuropathy
Unwillingness to continue participating in the study

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation method will be divided into 2 groups: 1- intervention with lidocaine spray along with Deltazax Powerice cooling spray and 2- intervention group with lidocaine spray alone. In order to randomly select 2 groups, dice will be used. Each of the samples will be placed in intervention group 1 if features 1, 2, 3 occur, and in intervention group 2 if features 4, 5, 6 occur. In the next step, the letter A (meaning intervention group 1) and letter B (meaning intervention group 2) will be placed in the envelope based on the choice made. For the first eligible person, envelope number one will be completed, and the envelopes will be given to the participants in order of number. and after opening the envelope, the type of individual group (intervention 1 and 2) was specified

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding is one-way blinding and the patient does not know the group she is in and the medicine used

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Azad University of Tehran
Medical Sciences Branch

Street address

Khaghani

City

Tehran

Province

Tehran

Postal code

1916893813

Approval date

2022-09-06, 1401/06/15

Ethics committee reference number

IR.IAU.TMU.REC.1401.179

Health conditions studied**1****Description of health condition studied**

Reduce the pain of iv catheterization

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain intensity during venipuncture

Timepoint

Immediately after venipuncture

Method of measurement

visual analog scale (VAS), 0-3 is mild pain, 4-6 is moderate pain, and 7-10 is severe pain.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: intervention with lidocaine spray along with Deltazax Power Ice cooling spray, for this

group, 10 puffs equivalent to 100 mg of 10% lidocaine solution (manufactured by Iran Daru Company) along with 10 puffs of Power Ice Deltaxax cooling spray (manufactured by Delta Daru Company) for a period of It will be used for 5 minutes on the location of vein extraction in a circle with a diameter of 3 cm. After two to three minutes, the target area will be disinfected with cotton and alcohol to a diameter of 5 cm. After 60 seconds, the vein will be taken by professional nurses. It will be done. All cases of venipuncture are performed with angioket number 21 in the middle cubital vein area. Lidocaine spray is an effective painkiller in mucous membranes. Lidocaine topical solution spray is one of the common forms of lidocaine for clinical use. Lidocaine spray has a medium effect and is used for local anesthesia of mucous membranes and skin. Cooling spray is an aerosol spray containing a volatile gas that evaporates in contact with the skin, its cooling effect is used to relieve pain. 10% lidocaine spray is used at the price of 473,000 rials per unit. Power Ice Deltaxax cooling spray is used for five units at the price of 620,000 rials per unit.

Category

Treatment - Drugs

2

Description

Intervention group 2: The intervention group is with lidocaine spray alone, in this group, 10 puffs equivalent to 100 mg of 10% lidocaine solution (manufactured by Iran Daru Company) alone for 5 minutes on the venipuncture site in a circular manner with a diameter of 3 cm meter will be used. After two to three minutes, the desired area will be disinfected with cotton and alcohol to a diameter of 5 cm, and after 60 seconds, the vein will be taken by professional nurses. It is performed in the middle cubital vein area. Lidocaine spray is an effective pain reliever for mucous membranes. Lidocaine topical solution spray is one of the common forms of lidocaine for clinical use. Lidocaine spray has a medium effect and is used for local anesthesia of mucous membranes and skin. Lidocaine spray 10% is used at the price of 473,000 rials per unit.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان بوعلی

Full name of responsible person

Masoumeh moallem

Street address

Tehran, Imam Hossein Square, the beginning of Damavand St

City

Tehran

Province

Tehran

Postal code

1711734365

Phone

+98 21 3334 8036

Fax

+98 21 3378 6182

Email

booali.hospital96@gmail.com

Web page address

<https://tms.iau.ir/bouali/fa>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Alireza khoshdel

Street address

Khaghani

City

Tehran

Province

Tehran

Postal code

1916893813

Phone

+98 21 2200 6660

Fax

+98 21 2660 2642

Email

Pezeshkitechran.8@gmail.com

Web page address

<https://tms.iau.ir/fa>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Islamic Azad University

Proportion provided by this source

20

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Masoumeh Moallm

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Vahid dastgerdi

City

Tehran

Province

Tehran

Postal code

1918613511

Phone

+98 21 2222 3567

Email

masoumehmoallem@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Shima mosalanejad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Khage abdolah

City

Tehran

Province

Tehran

Postal code

16611645320

Phone

+98 21 2232 2780

Email

Shimaamosalanejad@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Masoumeh moallem

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

General Practitioner

Street address

Vahid dastgerdi

City

Tehran

Province

Tehran

Postal code

1918613511

Phone

+98 21 2222 3567

Email

Masoumehmoallem@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There are currently no plans to publish.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available